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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,748	09/27/2005	Joel E White	700355-052696	9053
50828 DAVID S. RES	7590 07/25/200 NICK	EXAMINER		
NIXON PEABODY LLP			SKOWRONEK, KARLHEINZ R	
100 SUMMER STREET BOSTON, MA 02110-2131			ART UNIT	PAPER NUMBER
			1631	
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			07/25/2008	ELECTRONIC

# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

bostonpatent@nixonpeabody.com mstembridge@nixonpeabody.com

	Application No.	Applicant(s)		
	10/535,748	WHITE ET AL.		
Office Action Summary	Examiner	Art Unit		
	KARLHEINZ R. SKOWRONE	K 1631		
The MAILING DATE of this commun Period for Reply	ication appears on the cover sheet with	the correspondence address		
A SHORTENED STATUTORY PERIOD F WHICHEVER IS LONGER, FROM THE M - Extensions of time may be available under the provisions after SIX (6) MONTHS from the mailing date of this comn - If NO period for reply is specified above, the maximum st - Failure to reply within the set or extended period for reply Any reply received by the Office later than three months a earned patent term adjustment. See 37 CFR 1.704(b).	AILING DATE OF THIS COMMUNICA of 37 CFR 1.136(a). In no event, however, may a reply nunication. atutory period will apply and will expire SIX (6) MONTHS will, by statute, cause the application to become ABANI	TION.  be timely filed  from the mailing date of this communication.  DONED (35 U.S.C. § 133).		
Status				
3) Since this application is in condition	ed on <u>02 May 2008</u> . 2b) This action is non-final. for allowance except for formal matters ce under <i>Ex parte Quayle</i> , 1935 C.D. 1			
Disposition of Claims				
4) ☐ Claim(s) 19-29 is/are pending in the 4a) Of the above claim(s) is/a 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 19-29 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restrict  Application Papers	re withdrawn from consideration.			
9) The specification is objected to by th	e Evaminer			
10) The drawing(s) filed on is/are:  Applicant may not request that any obje	a) accepted or b) objected to by ction to the drawing(s) be held in abeyance. the correction is required if the drawing(s)	See 37 CFR 1.85(a). is objected to. See 37 CFR 1.121(d).		
Priority under 35 U.S.C. § 119				
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>				
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (F 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	PTO-948) Paper No(s)/M	mary (PTO-413) ail Date mal Patent Application		

## **DETAILED ACTION**

### Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2 May 2008 has been entered.

### Claim Status

Claims 19-29 are pending.

Claims 1-18 are cancelled.

Claims 19-29 are being examined.

#### Declaration filed under 37 CFR 1.132

The declaration under 37 CFR 1.132 filed 7 April 2008 is insufficient to overcome the rejection of claims 19, 20, 21, 24, and 26-28 based upon Liebholz et al. (US Pat 7,029,852), in view of Melker et al.(US PGPUB 2002/0177232) and in view of Heynecker (US PAT 6,057,100) as set forth in the last Office action because: Declarant asserts at paragraph 15 that the substitution of the glass or plastic surfaces of Liebholz with the silk or fiber surfaces of Heynecker is not obvious because the Liebholz apparatus would be less efficient. To support this assertion, declarant states, at paragraph 13, that the surface should be solid because the particles must be impinged on the surface. Declarant also states at

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paragraph 14 that a skilled artisan would not substitute the solid surface of with a porous surface because such a surface would be much less efficient in capturing particles. Declarant's statement is not convincing because the device would still work as intended irrespective of the efficiency based on the substrate's porosity.

# Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential.35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

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- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The following rejection is necessitated by amendment.

Claim 19, 20, 21, 24, and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liebholz et al.(US Pat 7,029,852), in view of Melker et al.(US PGPUB 2002/0177232) and in view of Heynecker (US PAT 6,057,100).

The claims are drawn to a sensing system comprising a nucleic acid base sensor array; an excitation light source; a detector; a sample chamber; a sampling means; a controller means; and an analyte detection means. In another embodiment, the identification algorithm includes pattern matching and report generation. In another embodiment, the system is remotely controlled. In an embodiment the fibrous substrate is silk.

Liebholz et al. shows a sensing system for the detection and identification of analytes in an air sample. The system of Liebholz et al. is composed of a nucleic acid based sensor array formed through the use of multiple nucleic acid aptamers. The aptamers of Liebholz et al. are capable of detecting analytes. Liebholz et al. shows that the bioreceptor aptamers are on the substrate (col. 4, line 3-4). Thus, impingement of the analyte occurs as result recognition of the analyte by an aptamer (col. 5, line 30-37). Liebholz et al. teach that upon binding of analyte the aptamers produce a detectable signal. The signal is detected by a detector array (col. 4, line 66-67). The sensor array is housed within a sampling

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chamber that is combined with a sampling means to bring air into contact with the sensor array (col. 5, line 38-48). In figure 8, Liebholz et al. shows a microcontroller/ control means that is communication with the sampling means. The controller provides an analyte identification algorithm (col. 11, line 9-20). Liebholz et al. shows an embodiment in which the system is remotely controlled (figure 8). Liebholz et al. shows that a sampling algorithm is employed that opens or closes a trapdoor for a detector (col. 5 line 15-17). Liebholz et al. teach that the activation of the sensor array results a in a spatio-temporal response that is processed (col. 5, line 5-12). Liebholz et al. teach a processing system that produces a report.

Liebholz et al. do not teach a pattern matching that is a neural net or a nucleic acid array formed on a fibrous or particulate support.

Heynecker shows that nucleic acid microarrays can be formed on a number of different substrate. Heynecker shows that natural fibers such as silk are used a solid supports for microarray (col. 3, line 15-35).

Melker et al. teach the use of neural network for the generation of comparisons between the detected signal and a known pattern [0057].

It would have been obvious to modify the sensor apparatus of Liebholz et al. with the nucleic acid microarray substrates of Heynecker because all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective function; the combination would have yielded nothing more than predictable results to one of ordinary skill in the art at the time of the invention. It

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would have been further obvious to modify the sensing system of Liebholz et al. with the neural network analysis of patterns of Melker et al. because Melker et al. shows neural networks have the advantage of enabling the device to understand the significance of sensor array output [0057]. Neural networks are used for self-learning of computational devices.

## **Response to Arguments**

With regards to applicants remarks filed 7 April 2008, applicant argues that a skilled artisan would not make the modification of the apparatus of Liebholz et al. from using a solid substrate to the use of a porous substrate. To make the argument applicant relies on the declaration of Dr. Gary Settles. Applicant argues that the replacement of the solid support in the Liebholz et al. apparatus with a porous substrate of Heynecker et al. would make the function of the Liebholz et al. apparatus less efficient. The argument is not persuasive because porous and non-porous substrates of Liebholz et al. and Heynecker are solid substrates. Applicant has misconstrued and confused the teachings of Heynecker with the teachings of Liebholz et al. Liebholz et al. shows that porous filters can be used to filter larger particle from smaller particles such as vapors and particles (col. 4, lines 3-16). Heynecker shows a solid substrate surface that can be constructed from a plurality of materials, including silk, a porous solid substrate (col. 3, lines 16-35). Applicant argues that one of ordinary skill would not have made the modification to replace the glass solid substrate of Liebholz to use a silken solid substrate of Heynecker. The argument is not persuasive because Heynecker shows that silk as well as a plurality of other materials are

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suitable as solid supports. The argument is not persuasive and the rejections are maintained.

Claims 20, 22 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liebholz et al. (US Pat 7,029,852), in view of Melker et al. (US PGPUB 2002/0177232) and in view of Heynecker (US PAT 6,057,100) as applied to claims 19, 20, 21, 24, and 26- 28 above, and further in view of Sunshine et al. (US pat 6,234,006).

The claims are drawn to a sensing system comprising a nucleic acid base sensor array; an excitation light source; a detector; a sample chamber; a sampling means; a controller means; and an analyte detection means. In another embodiment, the identification algorithm includes pattern matching and report generation. In another embodiment, the system is remotely controlled.

Liebholz et al. in view of Melker et al. and in view of Heynecker as applied to claims 19, 20, 21, 24 and 26-28 shows a sensing system for the detection and identification of analytes in an air sample. The system of Liebholz et al. is composed of a nucleic acid based sensor array formed through the use of multiple nucleic acid aptamers. The aptamers of Liebholz et al. are capable of detecting analytes. Liebholz et al. teach that upon binding of analyte the aptamers produce a detectable signal. The signal is detected by a detector array (col. 4, line 66-67). The sensor array is housed within a sampling chamber that is combined with a sampling means to bring air into contact with the sensor array (col. 5, line 38-48). In figure 8, Liebholz et al. shows a microcontroller/ control

means that is communication with the sampling means. The controller provides an analyte identification algorithm (col. 11, line 9-20). Liebholz et al. shows an embodiment in which the system is remotely controlled (figure 8). Liebholz et al. shows that a sampling algorithm is employed that opens or closes a trapdoor for a detector (col. 5 line 15-17). Liebholz et al. teach that the activation of the sensor array results a in a spatio-temporal response that is processed (col. 5, line 5-12). Liebholz et al. teach a processing system that produces a report.

Liebholz et al. in view of Melker et al. and in view of Heynecker as applied to claims 19, 20, 21, 24 and 26-28 does not shows a sensing system that is specifically attached to a shipping container or that is hand held.

Sunshine et al. shows the application of a sensing system to a shipping container (col.24, line 51-52 and col. 25, line 27-28). Sunshine et al. shows a sensing system that is hand held (col. 2, line 60).

It would have been further obvious to modify the sensing system of Liebholz et al. in view of Melker et al. and in view of Heynecker with the portability of a handheld apparatus because Sunshine et al. shows that a handheld system provides the advantage of being small and light weight (abstract).

# Response to Arguments

Applicant's arguments filed 7 April 2008 have been fully considered but they are not persuasive. Applicant argues that a skilled artisan would not make the modification of the apparatus of Liebholz et al. from using a solid substrate to the use of a porous substrate. The argument is not persuasive for the reasons

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provided above for Liebholz et al. (US Pat 7,029,852), in view of Melker et al.(US PGPUB 2002/0177232) and in view of Heynecker (US PAT 6,057,100) as applied to claims 19, 20, 21, 24, and 26- 28 above. The rejection is maintained.

Claims 20 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liebholz et al.(US Pat 7,029,852), in view of Melker et al.(US PGPUB 2002/0177232) and in view of Heynecker (US PAT 6,057,100) as applied to claims 19, 20, 21, 24 and 26-28 above, and further in view of Vivekananda (US PGPUB 2004/0023266).

The claims are drawn to a sensing system comprising a nucleic acid base sensor array; an excitation light source; a detector; a sample chamber; a sampling means; a controller means; and an analyte detection means. In another embodiment, the identification algorithm includes pattern matching and report generation. In another embodiment, the system is remotely controlled.

Liebholz et al. in view of Melker et al. and in view of Heynecker as applied to claims 19, 20, 21, 24 and 26-28 shows a sensing system for the detection and identification of analytes in an air sample. The system of Liebholz et al. is composed of a nucleic acid based sensor array formed through the use of multiple nucleic acid aptamers. The aptamers of Liebholz et al. are capable of detecting analytes. Liebholz et al. teach that upon binding of analyte the aptamers produce a detectable signal. The signal is detected by a detector array (col. 4, line 66-67). The sensor array is housed within a sampling chamber that is combined with a sampling means to bring air into contact with the sensor array

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(col. 5, line 38-48). In figure 8, Liebholz et al. shows a microcontroller/ control means that is communication with the sampling means. The controller provides an analyte identification algorithm (col. 11, line 9-20). Liebholz et al. shows an embodiment in which the system is remotely controlled (figure 8). Liebholz et al. shows that a sampling algorithm is employed that opens or closes a trapdoor for a detector (col. 5 line 15-17). Liebholz et al. teach that the activation of the sensor array results a in a spatio-temporal response that is processed (col. 5, line 5-12). Liebholz et al. teach a processing system that produces a report.

Liebholz et al. in view of Melker et al. and in view of Heynecker as applied to claims 19, 20, 21, 24 and 26-28 does not shows a sensing system that is specifically attached to an X-ray screening machine.

Vivekananda et al. teach the system is applied to airport detection systems reading on X-ray screening machine [0029].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the sensing system of Liebholz et al. in view of Melker et al. and in view of Heynecker with the application of the sensing system to a shipping container as in Vivekananda et al. because Vivekananda et al. teach the device fulfils the need for a rapid and sensitive method to detect and identify pathogenic spores of anthrax [0010-0011].

## Response to Arguments

Applicant's arguments filed 7 April 2008 have been fully considered but they are not persuasive. Applicant argues that a skilled artisan would not make the modification of the apparatus of Liebholz et al. from using a solid substrate to

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the use of a porous substrate. The argument is not persuasive for the reasons provided above for Liebholz et al. (US Pat 7,029,852), in view of Melker et al.(US PGPUB 2002/0177232) and in view of Heynecker (US PAT 6,057,100) as applied to claims 19, 20, 21, 24, and 26- 28 above. The rejection is maintained.

Claims 19, 20, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liebholz et al. (US Pat 7,029,852), in view of Melker et al.(US PGPUB 2002/0177232) and in view of Heynecker (US PAT 6,057,100) as applied to claims 19, 20, 21, 24 and 26-28 above, and further in view of Klempner et al. (2002/0187464).

Claim 29 is directed to a substrate that is fiberglass.

Liebholz et al. in view of Melker et al. and in view of Heynecker as applied to claims 19, 20, 21, 24 and 26-28 above shows a sensing system with a microarray formed on a fibrous or particulate substrate.

Liebholz et al. in view of Melker et al. and in view of Heynecker as applied to claims 19, 20, 21, 24 and 26-28 above do not shows a substrate that is fiberglass.

Klempner et al. shows that microarray substrates can be formed from fiberglass [0049]. Klempner et al. shows that affinity ligand receptors can be oligonucleotides, reading on aptamers [0014]. Klempner et al. shows that the solid support can be particulate either beads, particles, or spheres.

It would have been obvious to one of ordinary skill in the art to modify the sensing apparatus of Liebholz et al. in view of Melker et al. and in view of

Heynecker as applied to claims 19, 20, 21, 24 and 26-28 above with the fiberglass substrate of Klempner et al. because the substitution of one type of solid support for another would have yielded predictable results.

## Response to Arguments

Applicant's arguments filed 7 April 2008 have been fully considered but they are not persuasive. Applicant argues that a skilled artisan would not make the modification of the apparatus of Liebholz et al. from using a solid substrate to the use of a porous substrate. The argument is not persuasive for the reasons provided above for Liebholz et al. (US Pat 7,029,852), in view of Melker et al.(US PGPUB 2002/0177232) and in view of Heynecker (US PAT 6,057,100) as applied to claims 19, 20, 21, 24, and 26- 28 above. The rejection is maintained.

### Conclusion

This is a RCE of applicant's earlier Application No. 10/535,748. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS**MADE FINAL even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory

period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KARLHEINZ R. SKOWRONEK whose telephone number is (571) 272-9047. The examiner can normally be reached on 8:00am-5:00pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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16 July 2008

/K. R. S./ Examiner, Art Unit 1631 /John S. Brusca/ Primary Examiner, Art Unit 1631